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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,673	11/09/2001	Gary B. Schneider	25080/04000	2448

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,673	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the election, received 3/11/04, in which applicant elected group III, claims 9-21 without traverse.

Claims 9-21 are pending.

Information Disclosure Statement

The information disclosure statements, received 5/21/02 and 4/29/03, are acknowledged. A signed copy is enclosed hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for activated form of vitamin D binding protein (ADBP) and fADP (SEQ ID NO:1) does not reasonably provide enablement for one or more DBP peptides and combinations thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated the promoting of bone deposition comprising administering a therapeutically effective amount of ADBP and fADBP. However, the claims broadly encompass administering one or more DBP peptides and combinations thereof for such in vivo use, which is clearly beyond the scope of the instant disclosure.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than using ADBP and fADBP, as shown in instant examples 1 and 2, page 18.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, first paragraph for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is rendered vague and indefinite by the phrase " administered at doses which are at least 10 fold greater than doses which have been shown to induce bone resorption in vivo" (lines 1-2). It is unclear as to the dosage applicant envisions for the instant agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (USPN 6,410,269).

The instant invention is drawn to a method for promoting bone deposition comprising administering to a mammalian subject a therapeutically effective amount of an agent selected from the group consisting of ADBP, one or more DBP peptides, and combinations thereof.

Yamamoto teaches administering a therapeutically effective amount of one or more vitamin D-binding proteins (DBP peptides)- e.g., SEQ ID NO: 2 which is a 95.6% query match with SEQ ID NO:1 of the instant application (see, e.g., instant SEQ ID NO:1- amino acids 1-14 and SEQ ID NO:2 of Yamamoto- amino acids 49-62) - see entire document including column 1, line 15- column 5, line 51; column 10, line 50- column 13, line 37; and claim 5. Yamamoto discloses vitamin D-binding protein (Gc protein) and its domain (domain III) were treated with immobilized beta-galactosidase and sialidase to yield macrophage activating factors (MAF), a protein with N-acetylgalactosamine as the remaining sugar moiety- see column 1, lines 36-38 and lines 41-42, and column 2, lines 46-47.

Please note that the instantly claimed functional effect would intrinsically occur upon administration, especially since the instantly claimed subject has not been qualified (i.e., the claims do not recite -- administering... to a mammalian subject in need thereof --). The result-effective adjustment in conventional working conditions (e.g., administering such peptides via conventional routes of administration such as injection, infusion, orally) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole is *prima facie* obvious over the reference, without evidence to the contrary.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE
PRIMARY EXAMINER